UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ELI LILLY AND COMPANY, Plaintiff, v. ACTAVIS ELIZABETH LLC, GLENMARK PHARMACEUTICALS INC., USA, SUN PHARMACEUTICAL INDUSTRIES LTD., SANDOZ INC., MYLAN PHARMACEUTICALS INC., APOTEX INC., AUROBINDO PHARMA LTD., TEVA PHARMACEUTICALS USA, INC., SYNTHON LABORATORIES, INC., ZYDUS PHARMACEUTICALS, USA, INC., Defendants.	Honorable Dennis M. Cavanaugh, U.S.D.J. Civil Action No. 07 CV 3770 (DMC) (MF) **Oral Argument Requested** **Return Date: To be set by the Court**

DEFENDANTS' BRIEF IN SUPPORT OF MOTION TO STRIKE EVIDENCE AND ARGUMENT INTRODUCED AT TRIAL RELATED TO FDA AND/OR REVIEW BOARD APPROVAL OF THE MGH PILOT STUDY OFFERED TO SUPPORT UTILITY

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I. INTRODUCTION

On the enablement/utility issue, this Court should strike all evidence and argument offered by Eli Lilly unless that evidence was properly disclosed in the specification of U.S. Patent No. 5,658,590 ("the '590 patent") or provided to the U.S. Patent & Trademark Office ("PTO") during prosecution. Specifically, Defendants move to strike all evidence of FDA permission to proceed or Institutional Review Board ("IRB") approval of the Massachusetts General Hospital ("MGH") pilot study, and any related testimony and argument.[1]

The Court has already addressed this issue. The Court concluded last December that "***[r]egardless of whether doctors at MGH and experts at the FDA recognized the invention's utility***, without providing the PTO with evidence of such recognition, Plaintiff cannot show that the patent credibly discloses utility." *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 676 F. Supp. 2d 352, 371 n.14 (D.N.J. 2009) (emphasis added). It is uncontested that Lilly never submitted ***any*** evidence related to the MGH study to the PTO. Given these facts, Lilly's purported evidence is entirely irrelevant and should be stricken.

The Court explained its rationale for disregarding this evidence to Lilly twice, holding that "there was essentially no ***initial*** disclosure of utility [in the '590 patent] to bolster with additional evidence." (Feb. 23, 2010 Op. Denying Lilly's Mot. for Recons. (D.E. 539) at 5 (emphasis added); *see also* May 13, 2010 Op. on Mots. in Limine (D.E. 621) at 10 n.7 ("[T]he '590 Patent specification made essentially no initial disclosure of utility.").)

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[1] The specific evidence and argument Defendants seek to exclude, by page and line number of the Trial Transcript, trial exhibit number, and page and line number of the designated deposition testimony, is set forth in Exhibit A to the accompanying Declaration of James S. Richter. In the event that the Court declines to grant Defendants' Motion to Strike, however, Defendants respectfully request that the Court consider all evidence listed in Exhibit A to the Richter Declaration.

Consequently, Lilly cannot attempt to satisfy the utility/enablement requirement with either "pre/post filing date test data" or other evidence it failed to disclose to the PTO. (May 13, 2010 Op. (D.E. 621) at 10, n.7; *see also* Feb. 23, 2010 Op. (D.E. 539) at 6-7 (reiterating that such evidence cannot establish utility where there was no credible disclosure of utility to begin with).)

Lilly nevertheless argues that the alleged IRB approval is somehow independently indicative that a person of ordinary skill in the art would have recognized atomoxetine's utility in treating ADHD. But in addition to the fact that this Court already resolved this issue, Lilly's evidence is legally irrelevant based on its own expert's admissions. Lilly's expert Dr. Pliszka conceded at trial that an IRB approval is a ***subjective determination*** made in balancing risks and potential benefits, "if any," to study participants. (See Defendants' Findings of Facts ("FOF") § IV, ¶¶ 62-64.) Such a subjective determination, which Dr. Pliszka acknowledged could change from one board to another (FOF § IV, ¶¶ 65-66)—and Dr. Pliszka had no idea who was on the MGH board—cannot substitute for the ***objective analysis*** required to determine if a skilled artisan would have accepted without question the '590 patent's claimed utility. At its core, Lilly's IRB evidence is pure speculation that adds nothing to the mix and should be stricken for that reason alone. Indeed, this subjective determination is rendered all the more irrelevant by Dr. Pliszka's admission at trial that "there doesn't have to be necessarily any benefits to the subjects" in order for an IND to be authorized by the FDA. (FOF § IV, ¶¶ 62-64.)

Finally, Lilly's IRB approval and FDA authorization evidence should be stricken for the independent reason that Lilly sandbagged Defendants on the eve of trial with its new theory and evidence of utility. At that point, it was much too late for Defendants to refute

Lilly's new theory with a medical ethics (or any other) expert. Magistrate Judge Falk, in an opinion adopted by this Court at trial, recognized that Lilly was alleging "a new and previously undisclosed theory" (Judge Falk's May 7, 2010 Op. (D.E. 617) at 13 n.4), and was attempting to have a previously undisclosed fact witness, Dr. Paul, testify in support of this theory. Judge Falk noted that Lilly's maneuvering and representations to the Court had an "air of desperation," and repeatedly described Dr. Paul's proposed testimony about the MGH IND as "expert testimony." (May 5, 2010 Hr'g Tr. at 28:21-29:4; 30:25; 33:7-9; 59:1-4; 91:21-24; 92:24-93:6.) Adopting Judge Falk's opinion, the Court held that Dr. Paul would not be permitted to offer "expert (or lay opinion) testimony." (May 7, 2010 Op. (D.E. 617) at 18; *see also* Trial Tr. 7:20-23.) Yet this is exactly what Lilly presented through Dr. Pliszka at trial, despite the fact that Lilly never offered or qualified Dr. Pliszka as an expert on this topic and admitted he had no first-hand knowledge of anything related to the MGH IRB or its approval of the pilot study.

For each or any of these several, independent reasons, Defendants respectfully request that the Court strike all evidence related to the alleged FDA or IRB approval of the MGH study as well as any related argument made by Lilly in support of its utility/enablement position.

II. BACKGROUND

A. The '590 Patent and the Court's Summary Judgment Ruling

The specification of the '590 patent is completely devoid of any test results to support its bald assertion that atomoxetine would be useful in the treatment of ADHD. In the absence of any such supporting experimental data, the Federal Circuit has held that a patent has sufficient supporting utility ***only*** when "one skilled in the art ***would accept without question*** statements as to the effects of the claimed drug products." *Rasmusson v. Smithkline Beecham Corp.*, 413 F.3d

1318, 1323 (Fed. Cir. 2005) (brackets omitted; emphasis added). Without either actual experimental evidence or a statement of utility that would not be questioned, "an applicant has failed to demonstrate sufficient utility and therefore cannot establish enablement." *Id.*

Here, Lilly has candidly admitted that no such data existed as of January 11, 1995, the '590 patent's filing date. (FOF § IV, ¶¶ 1, 3-4, 7.) Indeed, it was not until ***after*** the filing date of the '590 patent that Dr. Joseph Biederman and Dr. Thomas Spencer of MGH conducted a pilot study in which adults with ADHD were provided atomoxetine. (FOF § IV, ¶¶ 3-4.) It is undisputed that the MGH study was the first time anyone sought to ascertain whether atomoxetine could be used for treating ADHD. Id. Prior to that time, Dr. Heiligenstein (co-inventor of the '590 patent) admitted he had no idea whether atomoxetine could treat ADHD. (FOF § IV, ¶¶ 31-32.) And results from the pilot study were not obtained until approximately May 1995, months after Lilly filed the '590 patent application. (FOF § IV, ¶¶ 3-4.)

Without any pre-filing data to support the '590 patent's claimed ADHD utility, the '590 patent is necessarily invalid. Defendants have consistently maintained that Lilly is faced with an insoluble dilemma. It is impossible—logically, factually, and legally—for Lilly to prevail on ***both*** obviousness ***and*** enablement/utility. The '590 patent is thus necessarily invalid on ***at least*** one of those grounds. As a result, Defendants filed a motion for summary judgment of invalidity of the '590 patent, setting forth this argument. (*See* Mem. Supp. Defs.' Mot. for Summ. J. of Invalidity (D.E. 300) at 8-22.) In particular, Defendants argued that, "If the Court agrees with Lilly that the prior art is indeed confused and contradictory and cannot lead to a finding of obviousness, then it follows that one of ordinary skill in the art would not have

believed that atomoxetine would be effective in treating ADHD in the absence of experimental proof." (*Id.* at 22.)

In opposition, Lilly argued both that (1) the results of the MGH study could be used to support a finding that utility was properly disclosed, and (2) "doctors did find that utility [of the '590 patent was] credible, even before the patent was filed [as] the FDA granted permission to begin human clinical testing of atomoxetine for ADHD, and [MGH] physicians Drs. Biederman and Spencer agreed to conduct the trial." (Pl.'s Br. Regarding *In Re '318 Patent Infringement Litigation* (D.E. 482) at 1.) The Court disagreed.

Relying on binding Federal Circuit precedent, this Court held that "[the MGH] test results . . . cannot establish utility because they were not available at the time of the patent application's filing date." (Dec. 31, 2009 Am. Op. (D.E. 494) at 28); *Eli Lilly*, 676 F. Supp. 2d at 370. The Court also held that "[r]egardless of whether doctors at MGH and experts at the FDA recognized the invention's utility, ***without providing the PTO with evidence of such recognition***, Plaintiff cannot show that the patent credibly discloses utility." *Id.* at 371 n.14 (emphasis added). Thus, the very same evidence now at issue has already been rejected by the Court as irrelevant to the utility/enablement issue.

Lilly's new trial counsel thereafter moved for reconsideration, and specifically challenged the Court's decision with respect to the MGH and FDA evidence quoted above. (Pl.'s Mem. of Law Supp. Mot for Recons. (D.E. 500-1) at 11.) In denying Lilly's motion, the Court confirmed its summary judgment finding that the '590 patent did not ***disclose*** utility:

> This Court did not suggest that post-filing date test results could not properly be used to support an assertion of utility when such utility was in doubt. Here, however, there was essentially ***no initial disclosure of utility to bolster*** with additional evidence.

(Feb. 23, 2010 Op. (D.E. 539) at 5 (emphasis added).)

Nothing has changed. Lilly has not presented any new law that should cause the Court to reverse course.

B. The Evidence Presented at Trial Further Demonstrates that Lilly's Alleged "Approval Evidence" Is Irrelevant

In addition to failing to disclose test results—since none existed—the '590 patent's specification is also devoid of any analytical rationale to support the conclusorily asserted ADHD utility. The Court recognized this failure when it held that there was "essentially no initial disclosure" of utility in the '590 specification. In an attempt to prop up its patent, Lilly now seeks to use the alleged IRB approval to support its argument that a person of ordinary skill in the art would have believed that the drug was useful to treat ADHD. But as was clear from Dr. Pliszka's testimony, IRB approval proves nothing about what a person of ordinary skill would have thought of atomoxetine's utility in January 1995 for at least the following reasons:

- Dr. Pliszka testified that an IRB makes an "ethical judgment" about whether potential benefits, if any, outweigh any risks to patient participants—the "risk/benefit assessment is not a technical one valid under all circumstances." He agreed that an IRB's "ethical judgments" are "***subjective*** determinations" of risk and benefit. (FOF § IV, ¶¶ 62-64) Such ***subjective*** determinations have no bearing on the ***objective*** determination of whether a person of ordinary skill in the art would have understood the '590 patent to disclose credible utility.
- With regard to the make-up and qualifications of the IRB, Dr. Pliszka conceded he had no knowledge about the identities or backgrounds of the board members that reviewed the pilot study submission:

  Q. Okay. You don't know the identity of the board members who gave that approval; correct?

  A. I don't, no.

Q. Nor do you know whether any of them met your definition of ordinary skill in the art; correct?

***

A. I don't know for certain. (FOF § IV, ¶¶ 57-61.)

- With regard to the actual IRB decision to approve an IND, Dr. Pliszka testified:

Q. And it's also true consequently different IRBs may arrive at different assessments of a particular risk/benefit scenario?

A. That's right.

Q. IRBs make different judgments sometimes, depending on the credentials of the person making the request. Is that true?

A. That's true, yes. (FOF § IV, ¶¶ 65-66.)

Notably, in this case, the investigator asking for approval, Dr. Biederman, himself testified that he "had no idea" whether atomoxetine would work to treat ADHD. (FOF § IV, ¶¶ 73.)

- Dr. Pliszka also testified:

Q. Okay. Now, among all the documents that you looked at in this case, you have not seen a document that reports the reasoning of the IRB board in terms of calculating the risks and benefits of moving forward with this pilot study; correct?

A. Correct. (FOF § IV, ¶¶ 67.)

In the end, Dr. Pliszka merely speculated that the IRB must have concluded that there was "***a greater than zero percent chance***" that atomoxetine would treat ADHD. (FOF § IV, ¶¶ 71.) Given that Dr. Pliszka has no first-hand knowledge about the MGH board or its reasoning—and that his "greater than zero percent chance" conclusion means nothing in the context of whether a person of ordinary skill would "accept without question" atomoxetine's utility to treat ADHD—his IRB testimony is inadmissible speculation and irrelevant to any issue before the Court.

Moreover, Dr. Pliszka was only offered as an expert in the narrow field of "the science and treatment of ADHD," (Trial Tr. 788:15-20), and not as a medical ethics expert and, therefore, his testimony on medical ethics issues is improper evidence under Fed. R. Evid. 702. Indeed, as Defendants' noted at trial, Dr. Pliszka's expert reports disclose no opinions whatsoever about this notion that the IRB approval is somehow relevant to the utility issue.

Finally, it is significant that the record contains no evidence that the MGH IRB undertook any analysis at all regarding the MGH study before the filing date of the '590 patent application. Lilly introduced no evidence that the MGH IRB finally approved the MGH study before the filing date, and no evidence that the MGH IRB's provisional approval process involved any assessment of the proposed study's risks and anticipated benefits, thus further rendering Dr. Pliszka's testimony and Lilly's latest theory legally irrelevant speculation.

C. Lilly Should Not Be Permitted to Use Dr. Pliszka's Testimony to Circumvent the Court's Prior Ruling on Lilly's Attempt to Get the Same Evidence in through Dr. Paul

As noted above, Lilly shifted the focus of its utility argument in hopes of getting around the Court's prior rulings. Lilly's new argument is that the IRB approval and FDA authorization of the IND are not simply evidence that ***some*** doctors might have believed that atomoxetine could be used to treat ADHD, but that they are objective evidence that persons of ordinary skill in the art (persons who were ***unaware*** of the approvals) would have recognized that atomoxetine could be used to treat ADHD upon reading the 3-page '590 patent. Lilly's argument requires the Court to surmise, based on ethical codes and regulations, that FDA authorization to proceed and/or IRB approval was done by persons of ordinary skill in the art (however that person is ultimately defined by this Court) and necessarily means that such persons believed that the proposed testing was reasonably expected to succeed.

Lilly's new theory appeared for the first time—and then only obliquely—when Lilly put the ethics and regulatory codes referenced above on its exhibit list just weeks before trial. At the same time, Lilly put Dr. Paul on its witness list, allegedly to substitute for Dr. Watanabe, who had passed away some ten months before. (*See generally* Judge Falk's May 7, 2010 Op. (D.E. 617).) Lilly intended to have Dr. Paul provide "lay opinion" testimony regarding the MGH protocol and IND, as well as the FDA authorization and MGH IRB approval, to support its new theory of utility. According to Lilly (as quoted by the Court):

> The significance of those events to the alleged non-enablement defense here flows directly from the regulatory limitations imposed on the conduct of human drug testing. Every professional responsible for drug research is aware of these limitations and requirements. Dr. Watanabe of Lilly, had he lived, could have so testified from personal experience. *So can Dr. Paul in his stead*.

(*Id.* at 13 n.4 (emphasis in Court's Opinion).)

Judge Falk found that Lilly had violated its discovery obligations, and specifically noted that Lilly's "new theory" had just surfaced:

> There's no question that as far as I'm concerned, the interrogatories, what I saw this morning in terms of the interrogatories and the document request, and the 30(b)(6) notices were not properly responded to and were not updated in concept because in your briefing, your new theory came across, I don't believe that's tantamount to what is listed in Rule 26(a) and 26(e) about an initial disclosure update. I just want to make that clear.

(May 5, 2010 Hr'g Tr. at 85:7-14.)

Judge Falk also noted that "Dr. Paul's proffered lay opinion testimony appears to bear on scientific issues or otherwise specialized information that is not the proper subject of fact testimony." (May 7, 2010 Op. (D.E. 617) at 18, n.7 (citing *McCrary v. N.J. Transit Rail Operations*, No. 05-88, 2008 WL 2885872, at *3 (D.N.J. July 23, 2008) ("The Third Circuit and other courts have noted the global preclusion of any kind of lay opinion on specialized or technical subjects.") (citing *Estate of Edward W. Knoster v. Ford Motor Co.*, 200 Fed. Appx.

106, 111 n.3 (3d Cir. 2006))).)[2] In His Honor's Opinion, Judge Falk recommended, subject to this Court's approval, that Dr. Paul "should not be permitted to offer expert (or lay opinion) testimony." (May 7, 2010 Op. (D.E. 617) at 18).[3]

The Court did not preclude Dr. Paul from testifying as to factual issues contained in the proffer Lilly provided to the Court at its request, and ordered that Dr. Paul be produced for deposition. Yet once Judge Falk made clear that Dr. Paul could not offer opinion testimony, Lilly withdrew Dr. Paul from its witness list.

Over Defendants' objections (which the Court said Defendants could address through this motion to strike (Trial Tr. at 898:7-11)), Dr. Pliszka offered the very same opinion testimony that the Court precluded Dr. Paul from presenting. For example, Dr. Pliszka offered his belief that based on "general medical ethics," a physician treating a patient "must believe [a drug] should have some probability that it is going to improve the patient's symptoms and not have side effects that are so serious they outweigh the benefit," and further, that "those same ethical constraints apply in the environment of clinical trial testing of drugs in patients." (Trial Tr. 891:21-892:3; 892:11-13.) He also offered his opinion on the function of IRBs and the purpose of IRB approval, and testified as to what "standard practice" would be in conducting clinical trials. (Trial Tr. at 895, 899.) Dr. Pliszka was never offered or qualified as an expert on medical ethics or any related topic, and his expert report and deposition testimony are ***entirely***

[2] For example, Lilly's counsel said that Dr. Paul would testify generally about what it means to file an IND and "the significance of what that means, which is critical to the Court's determination given where we are on this issue of whether people of skill in the art at the time could believe and did believe that [atomoxetine] could be useful treating this disorder." (May 5, 2010 Hr'g Tr. at 28:16-20.) The Court responded that what Lilly described, "[s]ounds a lot like expert testimony." (*Id.* at 28:21.)

[3] This Court adopted Judge Falk's opinion and recommendation on the first day of trial. (Trial Tr. at 7:21-23).

devoid of any of the "facts" or opinions that he gave at trial regarding medical ethics and the IRB issue in clear violation of Fed. R. Evid. 702(1).

III. ARGUMENT

A. The Law of the Case Should Not Be Disturbed, and Requires Exclusion of the Alleged "Approval Evidence"

The Court has already held at least twice that evidence not provided to the PTO—whether it came into existence before or after the filing of the '590 patent application—cannot be used to establish utility. *Eli Lilly*, 676 F. Supp. at 371 n.14 ("Regardless of whether doctors at MGH and experts at the FDA recognized the invention's utility, without providing the PTO with evidence of such recognition, Plaintiff cannot show that the patent credibly discloses utility."); (May 13, 2010 Op. (D.E. 621) at 10 n.7) ("pre/post filing date test data" not presented to PTO cannot support finding that utility was credibly disclosed)).

This is the law of the case, and Lilly has not offered any reason—other than Lilly's displeasure with the Court's ruling—for the Court to overrule its prior holdings. There are no "extraordinary circumstances" warranting reconsideration. *See, e.g.*, *In re Gabapentin Patent Litig.*, 649 F. Supp. 2d 340, 356 n.18 (D.N.J. 2009) ("as a rule courts should be loathe to [revisit prior decisions] in the absence of extraordinary circumstances"); *In re City of Philadelphia Litig.*, 158 F.3d 711, 718 (3d Cir. 1998) (extraordinary circumstances exist where: "(1) new evidence is available; (2) a supervening new law has been announced; or (3) the earlier decision was clearly erroneous and would create manifest injustice"). In fact, the Court already took a second look at this issue, and came to the same correct conclusion, when

denying Lilly's motion for reconsideration of the Court's original summary judgment ruling.[4]

For this reason alone, Lilly's IRB-related evidence should be stricken.

B. Dr. Pliszka's IRB Testimony Is Speculative and Should Be Stricken

Lilly's evidence is additionally inadmissible because it is entirely speculative. According to Dr. Pliszka, the IRB approval means that one of ordinary skill would have recognized that atomoxetine would be useful to treat ADHD in January 1995—even though he himself testified to the exact opposite (that a skilled artisan would have believed the drug "was unlikely to work" (FOF § IV, ¶¶ 24)), and the inventor's own view refutes the claim (he testified that he no idea whether atomoxetine would treat ADHD (FOF § IV, ¶¶ 31-32)).

Dr. Pliszka's IRB opinion should be excluded because it is based solely on conjecture, and Dr. Pliszka never was accepted by the Court as an expert on this topic. "[I]f an expert opinion is based on speculation or conjecture, it may be stricken." *Fedorczyk v. Caribbean Cruise Lines, Ltd.*, 82 F.3d 69, 75 (3d Cir. 1996) (citation omitted). "A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). Courts examine an expert's conclusions "in order to determine whether they could reliably flow from the facts known to the expert and the methodology used." *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 153 (3d Cir. 1999). Fed. R. Evid. 702(1) likewise requires that expert testimony be based upon "sufficient facts or data."

[4] Defendants will not rehash the substantive arguments made by both sides here, as they were fully set forth in the parties' briefs on (1) Defendants' Motion for Summary Judgment of Invalidity (D.E. 294); (2) Lilly's Motion for Reconsideration (D.E. 500); and Defendants' Motion in Limine to Exclude Evidence of Post-Filing Date Test Data Used to Show Utility (D.E. 580). Defendants would be happy to provide additional briefing if requested by the Court and will be prepared to address any questions the Court may have at the July 2, 2010 hearing.

Here, Dr. Pliszka admitted he had no knowledge, from any source, of either the composition of the MGH IRB or the IRB's rationale for approving the MGH study. (FOF § IV, ¶¶ 57-61, 67) At best, he guessed the IRB board must have concluded that there was "*a greater than zero percent chance*" that atomoxetine would treat ADHD, but then admitted he had no basis for putting the number any higher. (FOF § IV, ¶¶ 71.) Indeed, Lilly, through Dr. Pliszka, is asking this Court to infer—really to ***assume***—a whole host of facts for which no evidence exists in order to reach his conclusion. Based only on medical ethics codes and IRB regulations, Dr. Pliszka would have the Court infer that the MGH IRB was composed of persons of ordinary skill in the art, that the IRB made a reasoned determination about the drug's utility in treating ADHD, and that the IRB's determination was based on a view of the prior art that was different from the Defendant's obviousness theory (since if that was their view, the alleged invention is obvious). But he testified that, in reality, he had no idea about the composition of the board and no clue as to their reasoning. He further testified that he (1) would not expect them to have reviewed the prior art; (2) that different boards could come to different conclusions; and (3) that the board's decision could very well have been influenced by the excellent reputation of Dr. Biederman. (FOF § IV, ¶¶ 65, 66, 72.) And neither he nor Lilly presented any evidence that the IRB completed its review or approval process prior to submission of the '590 patent application. Dr. Pliszka's opinion in support of Lilly's utility argument (whether considered expert or lay opinion) is nothing more than inadmissible speculation and conjecture and thus, should be stricken.

C. Lilly's Alleged "Approval Evidence" and Argument Should Be Stricken Because Lilly's Late Disclosure Prejudiced Defendants, Who Were Prevented from Presenting a Rebuttal Expert

If the Court were to credit any of Dr. Pliszka's testimony related to the IRB approval ***or even Lilly's argument on its late-disclosed theory***, Defendants would be severely

prejudiced. If Lilly had complied with its discovery obligations, Defendants could have obtained an expert (or experts) that would have put to rest any notion that approval of clinical trials equates to recognition of credible utility. The primary focus of any review board is to assess the ***safety*** of clinical trials. Defendants would have retained and presented a medical ethicist or expert on review board procedures and regulations to present this evidence affirmatively had Lilly disclosed its theory and evidence in response to Defendants' discovery requests.

Lilly recognized that Dr. Pliszka's expert report was devoid of the opinions they wished to elicit—which is why they tried to sneak Dr. Paul onto their witness list right before trial, hoping to have him offer opinions in the guise of fact and lay opinion testimony. When that gambit failed because the Court recognized the potential prejudice to Defendants and ***held that the proffered testimony was inadmissible opinion***, they simply forged ahead, and elicited the very same testimony from Dr. Pliszka. Again, there is no reason for the Court to revisit its prior rulings. Dr. Pliszka's testimony related to IRB approval is identical to that Lilly proposed to elicit through Dr. Paul. The former should be held inadmissible just as was the latter.

IV. CONCLUSION

Lilly's IRB evidence and argument is legally irrelevant, entirely speculative, and prejudicial because of its late disclosure. For each of these reasons—and based on the law of the case—Defendants respectfully request that the Court strike it from the trial record.

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